REMARKS

The Office Action dated October 20, 2004, has been received and reviewed. Claims 1-48 are pending in the present application. Claims 1-46 stand rejected. Independent Claims 1, 12, 22, 29, 34 and 41 have been amended to distinguish that the drugs administered included one those selected from the group consisting of a calcium channel blocker, a calmodulin blocker and a calmodulin kinase inhibitor, in combination with an antiarrhythmic drug. Claim 13 has been canceled without prejudice or disclaimer. Claim 4 has been amended to ensure consistency with the remaining claims. Claim 12 has been amended to include the recitations of Claim 13. Claims 22 and 34 have also been amended to similarly include these recitations, which may also be found in paragraph 65 of the specification. Claim 41 has also been amended along similar lines and to correct a typographical error. Claims 47-48 are withdrawn from consideration based upon a restriction requirement. Applicants affirm they with wish to prosecute Claims 1-46. Applicants respectfully request reconsideration of the application in view of the amendments made and the arguments below.

I. Drawings

Applicants are submitting formal replacement drawings under separate cover herewith to obviate the Examiner's objection to the drawings filed with the application. Applicants have removed "94" from Figure 3 and the specification, and have revised the specification, paragraph 55, to note that "92", previously "92" and "94" is a wire or a catheter. Applicants have revised Figure 5 to note that "170" is a "fibrillation detector" rather than a "synchronization monitor". Applicants note that the changes to Figure 5 are contained in paragraph 62 of the present application and thus this change does not include new matter. Accordingly, Applicants request that the objections to the drawings be withdrawn.

Applicants have amended the specification to remove references to 51, 53 and 55 and have amended reference 16 to read "116". Applicants further note that reference 116 was listed in the specification in paragraph 59. Applicants note that they have further amended the specification to comply with 37 CFR 1.84(p)(5) to include the reference characters 110, 133 and 148 in the specification. Reference characters 140, 142, 144 and 145 have been revised in FIG. 4 to read 40, 42, 44 and 45, respectfully, to mirror FIG. 3. Reference characters 176, 178, 180 and 182 have been revised in FIG. 5 to read 76, 78, 80 and 82, respectfully, to mirror FIG. 3. Applicants note that no new matter has been added with these amendments. Accordingly, Applicants request that the objections to the drawings be withdrawn.

II. Specification Objections

The specification has been objected to due to a typographical error in paragraph 53. Applicants have amended the specification as suggested by the Examiner. Accordingly, Applicants request that the objections to the specification be withdrawn.

Applicants have also amended the specification to comply with 37 CFR 1.84(p)(5) to include in the specification the numbers in the specification as noted above.

III. Claim Objections

Claims 16, 26, 33, 38 and 46 stand objected to for informalities. Applicants have amended these claims to include the word inhibitor after CaM kinase as suggested by the Examiner. Accordingly, Applicants request that the objections to Claims 16, 26, 33, 38 and 46 be withdrawn.

Claim 48 has been withdrawn thus mooting this rejection.

IV. Rejections under 35 U.S.C. § 102

A. Elsberry et al.

Claims 1, 5-6, 12-13 and 17-18 stand rejected as allegedly being anticipated by Elsberry et al., U.S. Patent No. 5,662,689. Applicants respectfully traverse this rejection as set forth below.

Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000).

Applicants submit that Elsberry et al. fails to disclose each and every element of Claims 1, 5-6, 12-13 and 17-18. Elsberry et al. purportedly discloses an implantable cardioverter for providing cardioversion electrical energy to a patient's heart in need of cardioversion and **applying a pain alleviating therapy** at an appropriate site in the patient's body prior to or in conjunction with the delivery of the cardioversion energy to the heart chamber to alleviate propagated pain. Applicants note that independent Claim 1, of which

Claims 5 and 6 depend, is directed to methods of decreasing shock strength required to treat an arrhythmia. Applicants note that Figure 7 of the application clearly illustrates that a combination of one of the drugs listed in Claim 1 with a defibrillation shock allows for a reduced shock strength. Thus, Claims 1 and 5-6 are directed to different methods than those disclosed by Elsberry et al. Applicants further note that Elsberry et al. discloses a drug pump 110 for "delivery of a cardioversion or defibrillation threshold reducing agent such as D-salotol, Procainamide or Quinidine as an alternative to or in conjunction with delivery of the pain alleviating therapies". However, these pain alleviating therapies are not the calcium channel blocker, a calmodulin blocker, or a calmodulin kinase inhibitor **and an** antiarrhythmic drug as recited in independent Claims 1 and 12. The pain relieving therapy of Elsberry et al. is an analgesic. Thus, Elsberry et al. does not disclose the combination of the calcium channel blocker, calmodulin blocker, or calmodulin kinase inhibitor in combination with an antiarrhythmic drug. Therefore, the recitations of Claims 1, 5-6, 12 and 17-18 are not anticipated by Elsberry et al. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections to Claims 1, 5-6, 12 and 17-18.

B. Kroll et al.

Claims 12, 14-15, 19, 21-25, 27, 34-35, 37 and 39 stand rejected as allegedly being anticipated by Kroll et al., U.S. Patent No. 5,925,066. Applicants respectfully disagree with this assessment. Independent Claims 12, 22 and 34, of which claims 14-15, 19, 21, 23-25, 27, 25, 27 and 37 depend from include the recitations that a therapeutic drug is administered with the therapeutic electric shock so that the strength of the shock is decreased as compared to the shock required to treat the arrhythmia in the absence of administration of the therapeutic drug. Kroll et al. purportedly discloses a memory implemented logic (software) to continuously monitor the atrial rate and initiate a response of either cardiac pacing, antitachycardia pacing or drug dispensing based on preset cardiac activity parameters. Applicants note that Kroll et al. does not disclose a device to decrease the strength of the shock nor does Kroll et al. disclose methods using such a device. Therefore, Applicants submit that Kroll et al. fails to anticipate each and every element in independent Claims 12, 22 and 34, of which claims 14-15, 19, 21, 23-25, 27, 25, 27 and 37 depend. Accordingly, Applicants respectfully request that the rejections to the claims based upon Kroll et al. be withdrawn.

C. Buscemi et al.

Claims 41-45 stand rejected as allegedly being anticipated by Buscemi et al., U.S. Patent No. 5,690,682. Applicants respectfully traverse this rejection. Buscemi et al. purportedly discloses an implantable programmable drug delivery system for injection of a pharmaceutical agent into the peritoneum to treat cardiac arrhythmia. Buscemi et al. does not disclose that its implantable programmable drug delivery system can include a therapeutic shock as recited in independent Claim 41 of the present application. Furthermore, Buscemi et al. fails to anticipate that the level of shock is decreased as compared to the shock required to treat said arrhythmia in the absence of administration of the calcium channel blocker, calmodulin blocker, or calmodulin kinase inhibitor combined with the antiarrhythmic drug. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections to Claims 41-45.

V. Rejections under 35 U.S.C. § 103

A. Elsberry et al.

Claims 2-3 and 7-10 are rejected as allegedly being obvious in view of Elsberry. Applicants traverse this rejection for the amended claims for the reasons set forth below.

To establish a prima facie case of obviousness, the prior art reference or references when combined must teach or suggest *all* the recitations of the claim, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). To support combining references, evidence of a suggestion, teaching, or motivation to combine must be clear and particular, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Court of Appeals for the Federal Circuit has also stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). Furthermore, as affirmed by the Court of Appeals for the Federal Circuit in *In re Sang-su Lee*, a factual question of motivation is material to patentability, **and cannot be**

resolved on subjective belief and unknown authority. *See In re Sang-su Lee*, 277 F.3d 1338 (Fed. Cir. 2002). Respectfully, as will be discussed below, the Official Action fails to meet the requirements for a prima facie showing of obviousness under § 103.

Elsberry et al. fails to teach or suggest the elements of Claims 2-3 and 7-10 of the present application. As noted above, Elsberry et al. does not disclose the combination of a calcium channel blocker, calmodulin blocker, or calmodulin kinase inhibitor in combination with an antiarrhythmic drug to decrease the shock strength of an arrhythmia. Again, Applicants note that Elsberry et al. discloses a pain alleviating therapy applying means which comprises a means for delivering a threshold reducing agent to the patient to allow reduction of the cardioversion energy delivered to the patient. The pain alleviating therapy of Elsberry et al. is an analgesic. Nowhere in their patent does Elsberry et al. teach or suggest the combination as claimed in Claims 2-3 and 7-10.

Applicants submit that Claims 7-10 are further allowable over Elsberry et al. as they disclose defrillation thresholds that are not taught or suggested by Elsberry et al. Applicants note that for a known ventricular arrhythmia, the energy of the defibrillation pulses are normally 34 joules. Claim 7 recites a method that contains less energy. Furthermore, Claims 8-10 all recite methods of reducing defibrillation threshold shock by certain percentages. Elsberry et al. fails to teach or suggest reducing percentages of in leading edge voltage through the calcium channel blocker, calmodulin blocker, or calmodulin kinase inhibitor and an antiarrhythmic drug as recited in the claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections to Claims 2-3 and 7-10.

B. Elsberry et al. in view of Anderson et al.

Claims 4, 11 and 29-33 are rejected as allegedly being obvious over Elsberry et al. in view of Anderson et al., U.S. Patent No. 6,518,245. Applicants respectfully traverse this rejection.

Applicants note that Anderson et al. either alone or in combination with Elsberry et al. fails to teach or suggest Claims 4, 11 and 29-33 of the present application. Anderson et al. purportedly discloses a method for treating or preventing arrhythmias in a human subject comprising the administration of an effective amount of a calcium/calmodulin-dependent protein kinase inhibitor. However, Anderson et al. fails to teach or suggest using a calcium/calmodulin-dependent protein kinase inhibitor in connection with a defibrillation shock or as a method to decrease the strength of a defibrillation shock. In fact, Anderson et

al. fails to even teach or suggest any type of reduction in the strength of a defibrillation shock.

Applicants further note that with respect to the delayed afterdepolarizations the induction and stability of reentry and its degeneration into fibrillation can be deceased by administering antiarrhythmic drugs that prolong the action such as ibutilide or dofetilide. Therefore, the administration of a drug that prevents delayed afterdepolarizations together with an antiarrhythmic drug that prolongs refractory periods and action potentials lowers the shock strength needed for defibrillation even more than either of the two drugs alone. Applicants submit that neither Elsberry et al. nor Anderson et al teach or suggest such the lowering of the shock strength with the two drugs recited in the independent claims of the present application. Accordingly, Applicants submit that the rejections to Claims 4, 11 and 29-33 should be withdrawn.

C. Kroll et al. in view of Anderson et al.

Claims 16, 26 and 38 are rejected as allegedly being obvious over Kroll in view of Anderson et al. Applicants respectfully traverse this rejection. Applicants submit that in addition to the reasons mentioned above, neither Kroll et al. nor Anderson et al. either alone or in combination teach or suggest Claims 16, 26 and 38. Again, Applicants point out that neither Kroll et al. nor Anderson et al. teach or suggest methods or devices for reducing the shock strength needed to treat an arrhythmia. Accordingly, Applicants submit that the rejections to Claims 16, 26 and 38 should be withdrawn.

D. Kroll et al.

Claims 20, 28, 36 and 40 are rejected as allegedly being obvious in view of Kroll. Applicants respectfully traverse this rejection. Applicants submit that in addition to the reasons mentioned above, Kroll et al. does not teach or suggest teach or suggest methods or devices for reducing the shock strength needed to treat an arrhythmia. Furthermore, Applicants submit that external versus internal devices are patentably distinct. Kroll et al. only discloses internal implementation of a device. This would exclude defibrillators used by emergency rescuers and the like. Therefore, internal and external devices are patentably distinct. Accordingly, Applicants submit that the rejections to Claims 20, 28, 36 and 40 should be withdrawn.

E. Buscemi et al. in view of Anderson et al.

Claim 46 is rejected as allegedly being obvious over Buscemi et al. in view of Anderson et al. Applicants respectfully traverse this rejection. Applicants submit that in addition to the reasons mentioned above, neither Buscemi et al. nor Anderson et al. either alone or in combination teach or suggest Claim 46. Again, Applicants point out that neither Buscemi et al. nor Anderson et al. teach or suggest methods or devices for reducing the shock strength needed to treat an arrhythmia. Accordingly, Applicants submit that the rejections to Claim 46 should be withdrawn.

CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 14, 2005.

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